App. No. 10/522,877 Docket No.: 0020-5340PUS1

### **AMENDMENTS TO THE CLAIMS**

## 1. - 5. (CANCELLED)

- 6. (Previously presented) A paste comprising, Bacillus Calmette-Guerin Cell Wall Skeleton (BCG-CWS) and squalane, wherein the paste comprises 6.6 g to 35.2 g of squalane per about 0.67 g of BCG-CWS and has the following properties:
  - (1) viscosity of between 0.2 and 0.7 poise at 25 °C.
- (2) comprising an assembly of BCG-CWS particles, wherein the particle diameter is from 0.1 $\mu$ m to 20  $\mu$ m in the particle size distribution and showing a single peak distribution with D10%: 0.23 +/- 0.05  $\mu$ m and D90%: 0.60 +/- 0.05  $\mu$ m.

#### 7. - 10. (CANCELLED)

- 11. (Previously presented) The paste according to claim 6, which is obtained by a process for preparation which comprises the following steps:
- (1) mixing the BCG-CWS and squalane in an organic solvent used as a dispersion-aiding solvent, wherein the organic solvent is hexane or heptane which comprises 5 to 20 (v/v) of ethanol; and
  - (2) a step of removing the organic solvent in (1) by distillation.

# 12. - 13. (CANCELLED)

14. (Previously presented) The paste according to claim 6 that is formulated as an oil-in-water emulsion, which comprises 0.66 g of the BCG-CWS, 0.4 wt% to 8wt% of the squalane, 0.01% to 3% of polyethyleneoxysorbitan fatty acid ester and 1 to 10% of mannitol per 2L of water.

#### 15. – 17. (CANCELLED)

18. (Previously presented) The paste according to claim 14, wherein the polyethyleneoxysorbitan fatty acid ester is TWEEN 80 (polysorbate 80).

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## 19. - 40. (CANCELLED)

- 41. (Original) A pharmaceutical composition comprising the emulsion according to claim 14.
- 42. (Previously presented) A pharmaceutical composition comprising the paste according to Claim 6 or 11.
- 43. (Previously presented) The paste according to Claim 6, wherein the paste has a viscosity between 0.43 and 0.55 poise at 25  $^{\circ}$ C.
- 44. (Previously presented) The paste according to Claim 6, wherein the paste has a viscosity of approximately 0.43 poise at 25 °C.
- 45. (Currently amended) The paste according to Claim 6, where the paste comprises 8.4 to 35.2 8.9 to 17.9 g of squalane per about 0.66g 0.67 g of BCG-CWS.
- 46. (Previously presented) A paste comprising Bacillus Calmette-Guerin Cell Wall Skeleton (BCG-CWS) and squalane, wherein the weight squalane: weight BCG-CWS of said paste is 9.8-52.5, and wherein the viscosity of said paste is between 0.2 and 0.7 poise at  $25^{\circ}$ C.
- 47. (Previously presented) The paste of claim 46, formulated as an assembly of BCG-CWS particles, wherein said particles have a diameter of between 0.1  $\mu$ M and 20  $\mu$ M, and wherein said assembly of particles has a single peak of particle size distribution with D10%: 0.23 +/- 0.5  $\mu$ M and D90%: 0.60 +/- 0.05  $\mu$ M.